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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/964,240	09/26/2001	Akiko Tanaka	3974.002	1854

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EXAMINER	
TATE, CHRISTOPHER ROBIN	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 10/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/964,240	Applicant(s) Tanaka et al.
	Examiner Christopher Tate	Art Unit 1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jul 28, 2003* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above, claim(s) *1, 2, and 13-16* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *3, 4, 7, 8, 11, 12, 17, and 18* is/are rejected.

7) ☒ Claim(s) *5, 6, 9, 10, and 19* is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The amendment filed July 28, 2003 is acknowledged and has been entered. Claims 3-12 and 17-19 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4 and 8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Amended claims 4 and 8 recite various particular types of vaccines, at least some of which are not supported by the original specification and claims and, thus, are deemed new matter. The alleged support for the amendments to claims 4 and 8 - i.e., paragraphs [0006-0008] of the instant specification - fails to provide an adequate written description (fails to provide adequate support) for most of the particular types of vaccines (e.g., "peptide vaccine", "protein vaccine", "live virus vaccine", "killed virus vaccine", "whole cell vaccine") recited in amended claims 4 and 8.

Applicant is required to cancel the new matter in the reply to this Office Action or to particularly point to adequate support for the limitations set forth above.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Sakagami et al. (US 4,985,249) or by Sham et al. (US 5,914,332).

A composition (adjuvant) comprising a pine cone extract is claimed.

Each of the cited references (to name a few) teach compositions comprising a pine cone extract (please note that such compositions could be used as adjuvants - i.e., nothing would preclude their use as such). Further, the intended use of the claimed product (e.g., as an adjuvant for administration of a nucleic acid vaccine) does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference compositions (see, e.g., MPEP 2112).

Therefore, each of the cited references is deemed to anticipate the instant claims above.

Claim Rejections - 35 U.S.C. § 103

Claims 3, 4, 7, 8, 11, 12, 17, and 18 are/stand rejected under 35 U.S.C. 103(a) as being unpatentable Sakagami et al. (US 4,985,249), in view of Sham et al. (US 5,914,332) for the reasons set forth in the previous Office action which are restated below.

Sakagami et al. teach anti-HIV, anti-tumor extract substances (which were effectively demonstrated *in vitro*) obtained from pine cones (termed KS-6 and KS-7: either of which also constitutes a medicament) - see entire document including claims. Sakagami et al. beneficially disclose it is highly probable that these extract substances might improve the condition of AIDS patients (due to their immunopotentiating activity) and their effect might be augmented by combinational treatment with other chemotherapeutic agents (see, e.g., col 4, line 52 - col 5, line 2). Sakagami et al. does not expressly teach incorporating such pine cone extracts within an anti-viral vaccine (such as an anti-HIV vaccine) or an anti-cancer vaccine.

Sham teaches an anti-HIV compound for administration to AIDS patients, whereby the compound may be administered in various pharmaceutical forms (e.g., orally, injectably) including incorporating a pharmaceutically acceptable adjuvant therein (see, e.g., col 72, line 65 - col 73, line 44). Sham also beneficially teaches that the compound can be administered in combination with a pine cone extract and/or with a vaccine such as one of various HIV vaccines (see, e.g., col 74, line 57 - col 75, line 67).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the pine cone extract agents taught by Sakagami et al. with other anti-HIV or other anti-cancer agents including an HIV vaccine component based upon the beneficial teachings provided by Sham, and also because Sakagami et al. expressly disclose that their pine cone extract substances provide beneficial immunopotentiating activity.

In addition, please note that it is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose (i.e., for treating HIV and/or cancer). The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). The adjustment of particular conventional working conditions (e.g., selecting a particular type of conventionally employed HIV vaccine, such as a nucleic acid HIV vaccine, for incorporation therein, and/or selecting a particular conventional means of administering such a composition, such as intramuscularly or via inhalation), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of clear and convincing evidence to the contrary.

Applicants' arguments with respect to the U.S.C. 103 rejection above have been carefully considered but are not deemed to be persuasive of error in the rejection. Applicants assert that neither Sakagami nor Sham use the term "adjuvant" in the immunologic sense but instead in the general sense. However, as discussed above, Sakagami et al. expressly disclose that their pine cone extract substances provide beneficial immunopotentiating activity and, thus, would it would have been obvious to one of ordinary skill in the art to combine the pine cone extracts taught by Sakagami et al. with other immunopotentiating agents (e.g., vaccines). Combining them in this manner would intrinsically allow the pine cone extract substances of Sakagami et al. to act as adjuvants to such vaccines. In addition, Applicants have argued and discussed the references individually without clearly addressing the combined teachings. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which make up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the references.

It is strongly suggested that claims 5, 9, and 19 be appropriately incorporated into claims 3, 7, and 17, respectively, so as to adequately distinguish (and define) the invention over the art.

Claim Objections

Claims 5, 6, 9, 10, and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment and actions necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

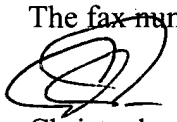
This application contains claims (1, 2, and 13-16) drawn to an invention nonelected with traverse in Paper No. 5. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (703) 305-7114. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached at (703) 306-3220. The Group receptionist may be reached at (703) 308-0196. The fax number for art unit 1654 is (703) 872-9306.



Christopher R. Tate
Primary Examiner, Group 1654